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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,419	06/07/2000	Tadashi Kohno	11127-002002	8455

26211 7590 01/24/2003

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1616

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/589,419

Applicant(s)

KOHNO ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5,7-9 and 43-63 is/are pending in the application.
- 4a) Of the above claim(s) 43-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 12, filed 11/8/02, wherein claims 1, 2, 4, 6, 10, and 11-24 were canceled; claims 3, 5, 7, and 9 were amended; and claims 43-63 were added.

Note: Claims 3, 5, 7-9, and 43-63 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 11/8/02 (Paper No. 9) to the rejection of claims 1, 4, 5, and 7-10 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Rejections

The 112 rejections are WITHDRAWN because Applicant has amended/canceled the claim of interest.

103 Rejection

The rejection of claims 3, 5, and 7-9 under 35 USC 103(a) as being unpatentable over Jindrich et al (Carbohydrate Research, 1995, Vol. 266, pages 75-80) in view of DeRosch et al (US Patent No. 5,300,280) is MAINTAINED for reasons of record in the office action mailed 6/4/02, Paper No. 10, and those set forth below.

Applicant asserts that Jindrich while disclosing a labeled cyclodextrin (13C-methyl labeled) does not disclose any other labeled cyclodextrins having a modified group as claimed by Applicant. Hence, 13C-methyl labeled cyclodextrin is not encompassed in the instant invention.

The amended claim is directed to a 13C-labeled poly- or oligo-saccharide comprising two possible components (1) 13C-cyclodextrin^{cyclon} OR (2) at least one sugar molecule of the poly- or oligo-saccharide that is modified with at least one modifying group (see independent claim 5). Hence, the prior art encompasses the instant invention because it discloses 13C-cyclodextrin. The cyclodextrin component of Applicant's claim does not require that it contain a modifying group. Furthermore, it is noted that claim 9 which depends upon independent claim 5 states that the 13C-labeled poly- or oligo-saccharide may be 13C-cyclodextrin or beta-galactosyl-13C-maltooligosaccharide. Thus, it is not required that the cyclodextrin be modified.

It is noted that Applicant asserts that DeRosch describes adding the cyclodextrin to the radiopharmaceutical kits, not radiolabeling the cyclodextrin directly.

DeRosch was cited because it discloses the use of both modified and unmodified cyclodextrins which the original claim required. In particular, it illustrates how cyclodextrins may be modified.

WITHDRAWN CLAIMS

3. Claims 43-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

Note: In particular, claims 43-63 are withdrawn from consideration because the search has not been extended beyond Group I which was elected *without traverse* in Paper No. 9, filed 3/20/02. Thus, as previously stated, Group I (now, pending claims 3, 5, and 7-9) comprises the *compounds/compositions* directed to a 13C-labeled

oligosaccharide or polysaccharide excluding U-13C-maltose, 13C-starch, 1-13C-maltotetraose, and 1-13C-amylose.

112 REJECTION

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 as written is ambiguous because it depends on canceled claim 6. Did Applicant intend to amend the claim to depend upon claim 5?

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to be 'D. L. Jones', with a stylized flourish at the end.

D. L. Jones
Primary Examiner
Art Unit 1616

January 21, 2003